

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K 2539	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DE98/00940	International filing date (day/month/year) 01 April 1998 (01.04.1998)	Priority date (day/month/year) 01 April 1997 (01.04.1997)
International Patent Classification (IPC) or national classification and IPC C12N 15/12		
Applicant DEUTSCHES KREBSFORSCHUNGSZENTRUM STIFTUNG DES ÖFFENTLICHEN RECHTS		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.  <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <u>2</u> sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 21 October 1998 (21.10.1998)	Date of completion of this report 23 July 1999 (23.07.1999)
Name and mailing address of the IPEA/EP European Patent Office D-80298 Munich, Germany Facsimile No. 49-89-2399-4465	Authorized officer  Telephone No. 49-89-2399-0

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE98/00940

## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

- ☐ the international application as originally filed.
- ☒ the description, pages 1-10, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims, Nos. \_\_\_\_\_, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. 1-11, filed with the letter of 16 July 1999 (16.07.1999),  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the drawings, sheets/fig 1/3-3/3, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	2, 4, 11	YES
	Claims	1, 3, 5-10	NO
Inventive step (IS)	Claims		YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

**2. Citations and explanations**

1. This report assumes that the claimed priority is valid. However, should this later prove not to be the case, various intermediate documents cited in the search report would become relevant prior art.

2. Pursuant to PCT Rule 5(ii), the description should indicate the underlying prior art, to the extent that this is considered useful for the examination. In the description of their application, the applicants do not cite a single prior art document.

Crucial information on the claimed subject matter of the application is also lacking. It is not even indicated how the protein with the arbitrary designation "FLIP" was obtained, or what DNA was used, for example, as a probe for finding out the claimed sequence depicted in Fig. 1. The examining authority considers that this indication is required for a conclusive examination of novelty and inventive step.

3. Nevertheless, this report will discuss the relevant prior art.

D1 (EMEST11 Database, Hillier et al., 1996) discloses an EST sequence which is 100% identical in 313 "overlapping" base pairs. Claim 3, which also comprises fragments (see points b and c), is therefore no longer novel (PCT Article 33(2)). D2 (Cell, Vol. 85, 1996, Muzio et al.) states that FLICE-induced cellular death is blocked by a wide spectrum of ICE inhibitors, such as, for example, pox virus z-VAD-7-fmk and CrmA. Since the wording of Claim 1 does not comprise a structural limitation ("having an amino acid sequence which differs therefrom by one or more amino acids" and "the DNA of the latter amino acid sequence being hybridised with the DNA of Fig. 1 under normal conditions"), but merely a functional limitation, the claim is not sufficiently delimited over the disclosure of D2, for example, which also describes inhibitors. The vague statement that the known inhibitors differ from the claimed inhibitor is, at best, sufficient to substantiate the novelty of the specific protein defined by the sequence, but certainly not that of the broader sequences. Claim 1 is therefore not novel (PCT Article 33(2)).

4. The PCT does not contain uniform criteria for assessing the industrial applicability of Claims 9-11 in their present form. Patentability can also depend on the wording of the claims. The EPO, for example, does not recognise industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment

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or to the use of such a compound in the manufacture of a drug for a new medical treatment. In the present case, however, an inventive step cannot be recognised in Claims 9-11 because the fields of application of the inhibitors are known to a person skilled in the art.

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**See the Separate Sheet.**